

## REMARKS

Upon entry of this amendment, claims 4-6 and 10-14 are pending in the instant application. Claims 1-3 have been cancelled herein without prejudice or disclaimer. Claim 4 has been amended, and Claims 11-14 have been added. Support for the claim amendment and new claims presented herein is found throughout the specification and in the claims as originally filed. For example, support for the new claims is found in the specification at least at page 4, lines 4-6. Accordingly, no new matter has been introduced.

### Claim Rejections Under 35 U.S.C. § 102

#### Au-Young *et al.*

Claims 1-6, 9 and 10 remain rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,500,938 by Au-Young *et al.* (“Au-Young”). According to the Examiner, although Applicants have amended the claims to recite colon, thyroid or renal cancer, such amendment to the preambles of claims 1 and 4 does not result in a manipulative difference between the claimed invention and the prior art.

Claim 1 and its dependent claims have been cancelled without prejudice. As amended, Independent claims 4 and 11 (and their dependent claims) are such that the recitation of the colon cancer, thyroid cancer and renal cancer cells continues to read on steps in the respective claims. As pointed previously, Au-Young does not specifically disclose or suggest using the specific subset of nucleic acids (which comprise SEQ ID NO:1 or encode a polypeptide comprising SEQ ID NO:2) or polypeptide (comprising SEQ ID NO:2) to identify the claimed subset of cancer cells (*i.e.*, from colon, thyroid and/or renal cancer). Accordingly, Applicants submit that this reference does not destroy the novelty of the claimed methods, and, as such, this rejection should be withdrawn.

#### Morin *et al.*

Claims 1-6, 9 and 10 remain rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0211498 by Morin *et al.* (“Morin”). In particular, the Examiner has indicated that Morin describes a nucleic acid sequence, SEQ ID NO: 53, that is

an ovarian cancer tumor marker that is identical to the nucleic acid sequence of SEQ ID NO:1 of the instant application, and Applicants' amendments to preambles of claims 1 and 4 are not sufficient to differentiate the instant invention from the prior art.

Again, the pending claims have been amended so that the recitation of the colon cancer, thyroid cancer and renal cancer continues to read on steps in the respective claims. As the Examiner seems to agree, Morin does not disclose or suggest methods of identifying colon cancer cells, thyroid cancer cells and/or renal cancer cells. Thus, the amended claims presented herein are novel over this reference. Applicants request, therefore, that the Examiner withdraw this rejection.

Gould-Rothberg *et al.*

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,436,642 by Gould-Rothberg et al ("Gould-Rothberg"). Specifically, the Examiner contends that Gould-Rothberg teaches human antileukoprotease is expressed in colorectal carcinomas and is up-regulated in metastatic thyroid cancer as compared to non-metastatic thyroid cancer.

Applicants respectfully submit that the pending claims are directed to a method of identifying colon cancer, thyroid cancer, or renal cancer cells in a test sample by comparing the expression of specific nucleic acids (comprising SEQ ID NO:1 or encoding a polypeptide comprising SEQ ID NO:2) or polypeptide (comprising SEQ ID NO:2) to their expression in corresponding normal tissues, where an **increase** in expression in the test sample indicates the presence of the cancer cells. In contrast, Gould-Rothberg simply teaches that human antileukoprotease was found to be expressed in colorectal cancer and thyroid cancer (upregulated in metastatic thyroid cancer as compared to the non-metastatic thyroid cancer). Gould-Rothberg does NOT teach that human antileukoprotease is **overexpressed** in colon cancer or thyroid cancer as compared to the corresponding normal tissues. There is no teaching or suggestions in Gould-Rothberg to identify a colon or thyroid cancer cell by detecting the overexpression of an antileukoprotease in a test sample as compared to a normal tissue. Accordingly, Gould-Rothberg does not teach the claimed invention, and this rejection should be withdrawn.

**Applicant: Rastelli *et al.***  
**U.S.S.N. 10/613,105**

### **CONCLUSION**

Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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